PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Tuesday, July 25, 2006, 10:00 a.m., at the John W. McCormack Building, One Ashburton Place, 21st Floor conference rooms, Boston, Massachusetts. Members present were: Chair Paul J. Cote, Jr., Commissioner, Department of Public Health, Clifford Askinazi, M.D., Atty. Michael C. Hanson, Ms. Soo J. Kim, Mr. Gaylord Thayer, Jr., and Martin J. Williams., M.D (arrived late during the staff presentation, therefore he did not vote on the May or June 2006 minutes). Atty. Jennifer A. Nassour, Ms. Maureen Pompeo, and Mr. Albert Sherman were absent. Also in attendance was First Deputy General Counsel Susan Stein, Acting as General Counsel of the Department of Public Health on behalf of Donna Levin who was absent.

Chair Cote announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Ms. Malena Hood, Epidemiologist, Research and Epidemiology Division, Center for Health Information, Statistics, Research, and Evaluation, Mr. Robert Walker, Director, Radiation Control Program, Ms. Joan Gorga, Acting Director, Determination of Need Program, Atty. Silva Cameron, Policy and Regulatory Development Specialist, Office of Emergency Medical Services, and the following Deputy General Counsels: Margaret Henehan, Carol Balulescu, and James Ballin.

RECORDS OF THE PUBLIC HEALTH COUNCIL MEETINGS OF MAY 23, 2006 AND JUNE 20, 2006:

Records of the Public Health Council Meetings of May 23, 2006 and June 20, 2006 were presented to the Public Health Council for approval. After consideration, upon motion made and duly seconded, it was voted unanimously (Dr. Williams not present to vote) to approve the Records of the Public Health Council Meetings of May 23, 2006 and June 20, 2006, as presented.

STAFF PRESENTATION: "MASSACHUSETTS DEATHS 2004", By Malena Hood, Epidemiologist, Research and Epidemiology Division, Center for Health Information Statistics, Research, and Evaluation

Ms. Malena Hood made the presentation on Massachusetts deaths. Highlights from the report follow (note: all death rates age-adjusted unless otherwise noted):

- Age-adjusted death rates fell to a record low of 739.3 deaths per 100,000 populations in 2004, down from 772.5 deaths per 100,000 in 2003, continuing a trend toward lower rates and mirroring a decline nationwide.

- In 2004, there was a continued decline in the number of resident deaths of 3% (1,775 deaths) from the previous year. This decrease was observed primarily among the group ages 65 and older, which had 1,416 fewer deaths.

- In 2004, heart disease, the leading cause of death, had a death rate significantly lower than in 2003 (182.8 vs. 196.6). Deaths rates due to the other nine leading causes of death (cancer, stroke, chronic lower respiratory disease, influenza and pneumonia, Alzheimer's disease, diabetes, unintentional injuries, nephritis, and septicemia), remained stable when compared with 2003 rates.

- Heart disease and cancer continued to be the leading causes of death among Massachusetts residents, accounting for half of all deaths. More women than men die of heart disease and cancer (the 2nd leading cause of deaths) in Massachusetts.

- In 2004, there were 211 Massachusetts residents who died from HIV/AIDS, which was one of the lowest annual numbers of HIV/AIDS deaths in Massachusetts (lowest years: 1997, 1998, and 2004) since the peak in the epidemic in 1994 (981 HIV/AIDS deaths). However, the proportion of HIV/AIDS deaths among women has nearly tripled since 1989 (28% vs. 11%), and the proportion of HIV/AIDS deaths for persons ages 45 and older has almost tripled since 1994 (57% vs. 20%).

- Life expectancy reached an all-time high in Massachusetts. In 2004, a new born girl born in Massachusetts could expect to live to be 82, and a new born boy 77.

- Injuries were the leading cause of death for Massachusetts residents between the ages of 1 and 44 years. Among the population overall, injuries rank as the fourth leading cause of death.

- About half of the leading cause-specific mortality rates are lower in Massachusetts than in the U.S. rates, including heart disease, stroke, and diabetes. Cancer and Alzheimer's age-adjusted deaths rates are about the same as those of the U.S., and injuries of undetermined intent much higher.

- While the homicide rate for Massachusetts in 2004 was about the same as it was in 2003, it has increased 40% since 2000. The black non-Hispanic homicide rate continued to be significantly higher than all other race and ethnicity groups.

- The suicide rate for Massachusetts in 2004 was about the same as it was in 2003. In 2004, the white non-Hispanic suicide rate was significantly higher than that of all other race and ethnicity groups.

- Although motor vehicle-related deaths were up by only 3 deaths, deaths to motorcyclists were up by 75%, from 40 deaths in 2003 to 70 deaths in 2004. The age-adjusted rate for motorcycle deaths increased significantly in 2004. This

increase was due entirely to an increase in male deaths.

- In 2004, the infant mortality rate (IMR) was 4.8 infant deaths per 1,000 live births, which continues the decline in IMR since 1980.

- As expected, in 2004, among Massachusetts residents most deaths occurred in the older age groups (75+ years) and the largest number of deaths continues to be among the oldest old (people aged 85 and over). About 1 out of 3 deaths is to a person age 85 or older (33%); almost 2 out of 3 deaths is to a person age 75 and older (64%).

- Disparities by race, ethnicity, and education persist:

    - ❖ The overall age-adjusted death rate for black non-Hispanics is 16% higher than the age-adjusted death rate for white non-Hispanics (866.2 vs. 744.7).

    - ❖ The death rate for those with a high school education or less was 3 times higher than the rate for those with 13 years of education or more.

    - ❖ The age-adjusted premature mortality rate (PMR) for black non-Hispanics (467.4) was higher that that of white non-Hispanics (320.7), Asian non-Hispanics (126.4), and Hispanics (273.1).

- Massachusetts has either achieved or moved closer to most of the Healthy People 2010 mortality objectives[1]. Out of 40 HP2010 mortality objectives examined, Massachusetts has achieved 16 targets and is within 25% of achieving targets for 9 additional indicators.

No Vote/Information Only

MISCELLANEOUS:

REQUEST FOR ADOPTION OF MAGISTRATE'S RECOMMENDED DECISION AS THE DEPARTMENT'S FINAL DECISION IN THE MATTER OF DPH VS. HEIDI SOUZA:

Attorney Margaret Henehan, Deputy General Counsel, Dept. of Public Health, presented the DPH vs. Heidi Souza case to the Council. She noted in part, "…Magistrate Maria Imparato recommended that Heidi Souza's certification to practice as an Emergency Medical Technician (EMT) at all levels be permanently revoked. The Magistrate based her recommendation on Ms. Souza's repeat violations of the Statewide Treatment

[1]In January 2000, the U.S. Department of Health and Human Services launched Healthy People 2010 (HP2010), a comprehensive, nationwide health promotion and disease prevention agenda. Healthy People 2010 contain 467 objectives; HP2010 has 46 mortality goals both using the underlying cause of death as well as other mentionable causes.

Protocols governing the delivery of pre-hospital medical care while employed at North Shore Ambulance Company. The Magistrate's also based her recommendations on criminal charges filed against Ms. Souza after she was found in a restricted area of the emergency room at Boston University Medical Center (BUMC) in possession of a hypodermic syringe and four vials of Diphenhydramine Hydrochloride (liquid Benadryl) hidden in her sock." DPH Agency Actions:

- On June 13, 2005, DPH filed the first agency action with the Division of Administrative Law Appeals (DALA) against Ms. Souza proposing a temporary revocation of her EMT paramedic certification based upon a complaint investigation finding that Ms. Souza violated the Statewide Treatment Protocols during an August 31, 2004 emergency response for a patient in ventricular tachycardia. This incident was one of four complaint investigations involving Ms. Souza's clinical skills. Ms. Souza requested a hearing and the matter was scheduled by DALA for an evidentiary hearing.

- The Department filed a second Agency Action with DALA against Ms. Souza on November 10, 2005, to immediately suspend her EMT certification after receiving notice that Boston University Medical Center (BUMC) had filed criminal complaints against Ms. Souza for Trespass; Larceny of a Controlled Substance and Possession of a Hypodermic Syringe.

- The Department learned that Ms. Souza had been terminated from Cataldo Ambulance Service after refusing a supervisor's request that she submit a urine screen, for cause -- Ms. Souza appearing to have an altered mental state while on call.

"Based upon these facts," said Atty. Henehan, "The Commissioner of Public Health determined that Ms. Souza's continued certification as an EMT posed a threat to the public health and safety and that an immediate suspension of her certification was warranted. The Department's second Agency Action sought a permanent revocation of Ms. Souza's EMT certification. Ms. Souza was required to surrender her EMT card at that time. She has not been able to practice as an EMT at any level since that date. Ms. Souza did not challenge the Commissioner's immediate suspension action but sought a hearing on the proposed permanent revocation. DALA consolidated both cases."

Administrative Magistrate Imparato conducted three days of hearing on March 10, March 16 and April 7, 2006. Ms. Souza was represented by Counsel. Both sides presented witnesses.

Atty. Henehan said further, "The Magistrate found with respect to the clinical care provided by Ms. Souza, that there were grounds for revocation of her certification pursuant to the regulations. With respect to the second agency action, the Magistrate characterized Ms. Souza's widely variant testimony as to why she took the vials of Benadryl as 'patently absurd and not credible.' Concluding that Ms. Souza went to BU Medical Center with the intention of stealing a controlled substance for non-medical use,

and that her conduct posed a danger to the public health and safety, as defined in our regulations."

In closing, Atty. Henehan said, "The Magistrate's decision does not become a final decision unless it is adopted by the Public Health Council. It is recommended that the Commissioner and the Public Health Council affirm and adopt the Magistrate's Recommended Decision as the Final Agency Decision in this matter."

On behalf of Ms. Souza, Attorney Tami M. Dristiliaris addressed the Council. She said, "…I am going to, on behalf of Heidi, make a plea to the Board that Heidi has been an EMT for twelve years, paramedic for eight of those years. She did very well in school. She went to the Northeastern University Program, did well clinically, as well as academically, and she is a wife and mother of four small children. She values her profession very highly. In a very short period of time, she had three clinical deficiencies presented to her. For the first two, she did provide the remediation that was required of her. She went to the classes, and got further training in the areas they thought she was deficient. For the third one, she denied that she did anything wrong on that day. She followed protocol as a guide. She did follow protocol to the best of the circumstances; and under the circumstances, the patient's symptoms warranted the treatment that she gave. She also stated that the patient had oxygen on. Apparently, her partner also testified to that fact. Her partner wasn't reprimanded for what he did on the scene that day. Two supervisory personnel were present at the scene to observe Heidi Souza and her partner perform most of their care on the patient…They had no criticism of them during the treatment and care of the patient, nor did they intervene at any time to say to them, why don't you try this or to say you are not doing that correctly…"

Attorney Dristiliaris continued, "Subsequent to that call, but after we had already applied for a hearing on the suspension of her license to practice as a paramedic, she had an unfortunate incident where she was at Boston Medical Center and as a result of that was found to be trespassing. The other charges were dropped. That case was continued without a finding. She did attend Narcotics Anonymous as a result of that. Heidi believes, at this time, that she is safe to practice as a paramedic. Short of repeating the entire paramedic course, she would do anything it takes to allow her to provide care to patients, to practice her profession, and to continue her livelihood, which she needs to provide for her family."

Council Member Hanson asked if Atty. Dristiliaris had any objections to the procedural process with the Magistrate. Atty. Dristiliaris responded, "I believe proper procedure was followed."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve and **adopt the Magistrate's Recommended Decision as the Department's Final Decision in the Matter of DPH v. Heidi Souza**.

REQUEST TO AMEND MDPH HOSPITAL'S ORGANIZATIONAL BYLAWS TO DESIGNATE THE QUALITY COMMITTEE A MEDICAL PEER REVIEW COMMITTEE PURSUANT TO M.G.L.C.111,§1:

Note: Council Member Askinazi recused himself from voting and discussion on this item.

Commissioner, Department of Public Health, Paul Cote, Chair, Public Health Council, explained the reason for docket item 2b to the Council. He said, "…We are putting forward this Bylaw change at the recommendation of the Medical Quality Committee of the Governing Board for all of our Public Health Hospitals. It is essentially a routine change, and one which is the unanimous recommendation of the Board of Governance, as well as the Quality Committee of the hospitals. Materials were forwarded to the members of the Public Health Council. May I have a motion to amend the Hospital Organization ByLaws as outlined in the materials distributed to the Council?"

After consideration, upon motion made and duly seconded, it was voted unanimously to approve the Request **To Amend MDPH Hospital's Organizational ByLaws to Designate the Quality Committee A Medical Peer Review Committee Pursuant to M.G.L.c.111,§1.** A copy of said material is attached and made a part of this record as **Exhibit No. 14,859.**

REGULATIONS:

REQUEST TO PROMULGATE PROPOSED AMENDMENTS TO 105 CMR 170.000: EMERGENCY MEDICAL SERVICES SYSTEM, FOR STATEWIDE EMS DATA COLLECTION:

Attorney Carol Balulescu, Deputy General Counsel, Department of Public Health, made the presentation on Emergency Medical Services System for statewide data collection to the Council. She was accompanied by Atty. Silva Cameron, Policy and Regulatory Development Specialist, from the Department's Office of Emergency Medical Services.

Attorney Balulescu indicated that the purpose of this request is for approval of an amendment to the Emergency Medical Services System regulation (105 CMR 170.000). The amendment updates requirements governing ambulance trip records to bring them into compliance with the National Highway Traffic Safety Administration (NHTSA)'s proposed dataset. Staff noted, "The new dataset called NEMSIS (National EMS Information System Dataset) follows a national standard that virtually all the states have committed to adopting. The benefits of such a data collection system include greatly enhanced quality assurance and quality improvement of all aspects of ambulance service operations and the delivery of patient care by EMS system."

The amendment deletes the existing general categories of elements that 105 CMR 170.345 currently requires be included, as a minimum, in each ambulance trip record, and instead requires that the trip record contain the data elements specified in an

Administrative Requirement (A/R) of the Department. The department is setting out the data elements in a sub-regulatory document in order to have the flexibility to incorporate any changes in the federal standards. The A/R has gone out for public review and comment to ambulance service providers. The Department will consider their comments and amend the A/R as appropriate before finalizing it. Under the proposed A/R for an interim period, ambulance services would continue to collect as a minimum dataset the same general categories of elements as they do under the current regulations, until the Department officially implements the date on which all ambulance services would need to collect the proposed statewide NEMSIS-compliant minimum dataset. The transition period will probably take about two years. The proposed statewide minimum dataset includes 147 of the over 400 NEMSIS data elements. The dataset includes data related to the responding ambulance, dispatch of that ambulance, times, scene information, patient care information, relevant medical history information, specific elements for trauma or cardiac arrest incidents, interventions performed, hospital destination and outcome linkage information. Many ambulance services are now collecting more than the elements in this proposed minimum dataset.

Staff noted in closing, "This regulatory requirement amends the very minimal broad categories of data elements currently required, and implements a requirement long sought by EMS system stakeholders – the mandate to collect comprehensive, standardized prehospital data across Massachusetts, and now across the country, in order to do effective quality assurance/quality improvement on all aspects of the provision of ambulance service and prehospital patient care. Moreover, having these data about EMS performance in Massachusetts will provide a stronger foundation for EMS training, the Statewide Treatment Protocols and policy development. Moving to do this by adopting a NEMSIS-compliant model achieves the even better result of joining nearly all the other U.S. states in collecting standardized EMS data across the nation."

A public hearing was held on June 26, 2006, one person testified in support of the amendment (Daniel Kane, Trauma Outreach Nurse, Dept. of Surgery, Beth Israel Deaconess Medical Center). Written comments were received from DPH staff suggesting additional data elements be included in the Department's A/R.

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the **Request to Promulgate Amendments to 105 CMR 170.000: Emergency Medical Services System, for statewide EMS Data Collection**; that a copy be attached and made a part of this record as **Exhibit No. 14,860**; and that the approved amendments be forwarded to the Secretary of the Commonwealth for publication in the Massachusetts Register on August 11, 2006. The amendment will become effective upon publication, which will meet the federal requirement that the regulation be in place by September 1, 2006.

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 120.000: MASSACHUSETTS REGULATIONS FOR THE CONTROL OF RADIATION:

Mr. Robert Walker, Director, Radiation Control Program, accompanied by Atty. James Ballin, Deputy General Counsel, Department of Public Health, presented the final amendments to 105 CMR 120.000 to the Council. Mr. Walker said in part, "…The existing set of comprehensive regulations pertaining to the control and use of radioactive material and radiation in the Commonwealth was first drafted by the Radiation Control Program (the "Program") in March of 1994, and approved by the Public Health Council on February 24, 1995. These regulations were last amended on July 9, 1999. Promulgating these comprehensive regulations was a necessary precursor for Massachusetts to achieve Agreement State Status with the Nuclear Regulatory Commission (NRC). An Agreement State is one to which the NRC legally transfers authority to regulate possession and use of most types of radioactive materials based on the state's agreement to maintain a comprehensive Radiation Control Program and to promulgate regulations that are compatible with, and at least as restrictive as, the NRC regulations. Periodic revisions of the regulations are necessary to adopt new compatibility requirements imposed by the NRC. The primary purpose of the current proposed revisions is to adopt in 105 CMR 120.500 new requirements imposed by the NRC in its regulations regarding the medical use of byproduct material (10 CFR Part 35). The overall goals of the revision are to implement NRC's regulations on those medical procedures that pose the highest risk to workers, patients and the public, and to structure the regulations to be more risk-informed and performance-based."

The Agency has revised 105 CMR 120.500 in its entirety due to the major changes made to 10 CFR Part 35. The proposed new 105 CMR 120.500 includes the following changes:

1. Deletion of the requirement that a licensee submit all required written procedures for review by the Agency.

2. Addition of a rule that requires the licensee to report a dose equivalent greater than 50 mSv (5 rems) to an embryo/fetus or nursing infant which is the result of administration of radioactive material or radiation from radioactive material to a pregnant individual or nursing mother.

3. Addition of rules for high-dose rate, pulsed-dose rate and low-dose rate remote afterloaders, and gamma stereotactic radiosurgey units.

4. Deletion of the requirement that all medical institutions must have a Radiation Safety Committee.

5. More stringent training and experience requirements for authorized users of unsealed radioactive material for therapy (with the exception of oral sodium 1-

131 users).

6. Less restrictive training and experience requirements for authorized users of oral sodium 1-131 in activities less than 33 mCi.

7. Addition of rules for the regulation of new medical uses of radioactive material (See 105 CMR 120.589).

8. Inclusion of the requirement that the preceptor authorized user must submit written certification that the individual has achieved a level of competency sufficient to independently function as an authorized user for the medical uses requested.

9. Reduction of duplicative rules that are also found in other parts (such as 105 CMR 120.200: Standards for Protection against Radiation).

Mr. Walker further said, "These revisions to the MRCR will not be increasing Massachusetts licensees' regulatory requirements. The revisions are intended to unify, clarify and simplify the regulatory requirements for licensees and make our MRCR requirements consistent with NRC and other jurisdictions."

In conclusion, Mr. Walker said, "The final regulations have been approved by the Office of the General Counsel of the Department of Public Health. We respectfully request the Council approve the regulations as amended for final promulgation." A brief discussion was held, whereby Council Member Hanson asked Mr. Walker if he felt the regulations were sufficient to protect the public health and safety in regards to radioactive material care, storage and security. Mr. Walker replied, "yes".

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the **Request for Final Promulgation of Amendments to 105 CMR 120.000: Massachusetts Regulations for the Control of Radiation**; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit No. 14,861.** A public hearing was held on August 31, 2005. There were no significant changes to the draft based on review of the comments.

REQUEST FOR EMERGENCY PROMULGATION OF AMENDMENTS TO 105 CMR 100.000: DETERMINATION OF NEED REGULATIONS GOVERNING FILING DAYS FOR APPLICATIONS FOR INNOVATIVE SERVICES AND NEW TECHNOLOGY:

Ms. Joan Gorga, Acting Director, Determination of Need Program, presented the request for emergency promulgation of amendments to 105 CMR 100.000 to the Council. She stated, "…This amendment changes the filing day of applications for Megavoltage Radiation Therapy Units from the first business day of August 2006 to the first business day of October 2006. The current emergency promulgation is necessary because the

Department is currently in the process of revising the Guidelines for Megavoltage Radiation Therapy Services. The final Guidelines are being separately presented to the Council for approval. Thus, the Guidelines will not have been completed in time for applicants to adequately plan for and prepare applications for the August 2006 filing day of Radiation Therapy applications."

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the request for **Emergency Promulgation of Amendment to Determination of Need Regulations 105 CMR 100.000 Governing Filing Days for Applications for Innovative Services and New Technology**; that a copy of the approved emergency regulation be forwarded to the Secretary of the Commonwealth; and that the approved emergency regulations be attached and made a part of this record as **Exhibit No. 14,862.** This amendment will be effective upon filing with the Secretary of the Commonwealth and will remain in effect for 90 days. A public hearing will be held on the proposed emergency amendment on August 21, 2006 at 10:00 a.m. Department staff anticipates returning to the September 19, 2006 meeting of the Council with the final version of the regulation for adoption.

DETERMINATION OF NEED PROGRAM:

GUIDELINES:

REQUEST FOR APPROVAL OF PROPOSED REVISIONS TO THE DETERMINATION OF NEED GUIDELINES FOR RADIATION THERAPY SERVICES:

Ms. Joan Gorga, Acting Director, Determination of Need Program, presented the revisions to the DoN Guidelines for Radiation Therapy Services to the Council. Ms. Gorga said, "…We request the Council's adoption of the revisions to the Determination of Need Guidelines for Megavoltage Radiation Therapy Services, which were adopted by the Council on December 29, 1999. The revisions are technical changes that result from more current (2002) cancer incidence data from the Massachusetts Cancer Registry and 2010 census-based population projections, which were not available when the Guidelines were prepared. The technical changes result in a projected need for 68 Radiation Therapy units in the year 2010. After adjusting for existing capacity (including the units approved under 105 CMR 100.308 Special Exemptions but not the units approved as expansion units for existing services under the 1999 revisions to the Guidelines), the Department calculates a statewide need for eight units by the year 2010 as indicated in Exhibit III of the Attachment to staff's memorandum to the Council, dated July 25, 2006. New and innovative uses of radiation therapy, which include but are not limited to intraoperative radiation therapy and stereotactic radiosurgery, are not included in the total state capacity since the Guidelines indicate that these units are to be considered outside the need calculations."

Ms. Gorga said further, "The Department has decided to update the need projections to the year 2010 to ensure that patients will continue to receive treatment in a timely and

efficacious manner. Approval of the eight additional units will improve geographic access of radiation therapy services to new patients statewide. The revised guidelines were released for public comment on June 21, 2006." Comments were received from the Massachusetts Hospital Association, Caritas Christi Health Care, Jordan Hospital, Cape Cod Hospital, and Southcoast Hospitals Group. (See staff memorandum dated July 25, 2006, issued July 17, 2006 for comments and staff response).

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the **Request for Adoption of Revisions to the Determination of Need Guidelines for Megavoltage Radiation Therapy Services**.

The meeting adjourned at 10:55 a.m.

LMH/lmh

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Paul J. Cote, Chair